TRANSMITTAL SLIP	DATE 20 Sept 84
TO: Executive Secretary	
ROOM NO.	BUILDING
REMARKS:	

This has been coordinated with OGC.

Ref: ER 84-6113

FROM: OMS		
ROOM NO. 1D4061	BUILDING Hqs.	EXTENSION

FORM NO. 0-4-1 REPLACES FORM 36-8 (47)

Central Intelligence Agency

ER 84-6113/1

Washington, D.C. 20505

20 SEP 1984

The Honorable George A. Keyworth, II
Science Advisor to the President
Executive Office of the President
Office of Science Technology Policy
Washington, D.C. 20506

Dear Dr. Keyworth:

This is in response to your request of 21 August 1984 for our views on the revised Model Policy for the Protection of Human Subjects. As we have previously indicated to the Interagency Human Subjects Coordinating Committee, although we fully concur with the principles established in the Model Policy, we will be unable to adopt the Model Policy until we are authorized by the Department of Health and Human Services regulations to do so. Therefore, the Agency must continue to adhere to the following departure from the Model Policy:

> The Central Intelligence Agency (CIA) is required by Executive Order 12333 to conform to the guidelines issued by the Department of Health and Human Services (HHS). Currently, the CIA follows the HHS regulations codified in 45 C.F.R. 46. If, with respect to the CIA, HHS incorporates the model policy, the CIA will follow the model policy. The CIA fully concurs with the principles established in the model policy.

If you have any questions regarding our position, please contact me at [redacted] STAT

Sincerely,

(Signed)

STAT [redacted]

Chairman, CIA Human Subject Research Panel

Distribution:
Orig - Addressee
1 - ER
1 - EO/DDA
1 - D/OMS

DCI EXEC REG

1-299

EXECUTIVE SECRETARIAT

ROUTING SLIP

TO:		ACTION	INFO	DATE	INITIAL
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7	DDO				
8	DDS&T				
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10	GC				
11	IG				
12	Compt				
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14	D/OLL				
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22					
	SUSPENSE		Date		

Remarks

For direct response pls coord with wfo
Copy to ES.

STAT

Executive Secretary

9/6/84
Date

3637 (10-81)

Aff. ER83-3729/1+2

THE WHITE HOUSE

WASHINGTON

August 21, 1984

MEMORANDUM FOR DISTRIBUTION

FROM: G. A. Keyworth

SUBJECT: Department and Agency Clearance of the Model Policy for the Protection of Human Subjects and Other Responses to Recommendations of the President's Commission

In response to my memorandum of July 18, 1983, you concurred in a Model Policy for the protection of human subjects of research developed by an Interagency Ad Hoc Committee for Protection of Human Subjects chaired by Dr. Edward N. Brandt, Jr., the Department of Health and Human Services (HHS) Assistant Secretary for Health (Tab A). In indicating concurrences, several of you identified proposed departures from the Model Policy due to statutory requirements or other department and agency needs.

Subsequently, in October 1983 I chartered the Interagency Human Subjects Coordinating Committee under the Federal Coordinating Council for Science, Engineering, and Technology with representatives from each department and agency and several Ex Officio members. Members of this group, my staff, and Office of Management and Budget (OMB) staff, recommended refinements in the Model Policy. I have reviewed these and believe they will improve the Model Policy and will ensure greater uniformity. I request that you review these changes and signify concurrence with the Model Policy--as modified--before it is published in the rulemaking section of the Federal Register as a Notice of Proposed Model Policy. The following steps outline the plan for implementation.

First, I request your concurrence in the revised Model Policy for the Protection of Human Subjects found in Tab B. Please review any departures you specified earlier. You may (1) concur with the Model Policy without departure; or (2) reaffirm or adjust those departures that you consider essential. The changes that have been made in the Model Policy should obviate the need for many of the departures previously included. Only when statutory or other essential program needs exist are departures justifiable. It is important that you specify at this time any departures that you propose to make when you implement the Model Policy. Although Sec.101(i) permits department and agency heads to waive provisions

of the Model Policy, it is intended that waivers be used sparingly and only in exceptional circumstances.

Second, the other Responses to the Recommendations of the President's Commission, which were modified to accommodate changes in the revised Model Policy, will also be published by the Office of Science and Technology Policy (OSTP) on behalf of the affected departments and agencies.

Third, upon receipt of all concurrences, OSTP will publish the Model Policy, all proposed departures and the Responses as a Notice of Proposed Model Policy. A public comment period will follow.

Fourth, the Model Policy, modified in light of public comments and recommendations to me by the Interagency Human Subjects Coordinating Committee, will be published by OSTP as a Final Model Policy. No departures will be published at that time. To the extent that public comment is favorable to departures that have applicability to more than one department or agency, such departures may be incorporated into the Final Model Policy.

Fifth, OSTP plans to publish the Final Model Policy within 90 days after the close of the public comment period. Subsequently, each department and agency should prepare its own implementing rules through rulemaking or other customary policymaking procedures for simultaneous publication. Departments and agencies may publish the policy by replicating or referencing the final publication that appears in the Federal Register. As required by E.O. 12291, rulemaking issuances must be submitted to OMB for review. OMB advises us that they will analyze carefully public comments and proposed departures as part of its E.O. 12291 reviews of department and agency implementing rules.

We are now close to publishing an important proposed Model Policy for the protection of human research subjects. I very much appreciate your and your staffs cooperation in this major effort. Your responses to this request for concurrence in the Model Policy and specification of any proposed departures should be sent to my office on or before September 20, 1984, [30 days] to the attention of Dr. Bernadine H. Bulkley, Deputy Director, Office of Science and Technology Policy, New Executive Office Building, Room 5005, Washington, D.C. 20506; the telephone number is (202) 395-5101.

Thank you for your continued cooperation.

Attachments

DISTRIBUTION

The Honorable M. Peter McPherson, AID
The Honorable William J. Casey, CIA
The Honorable Nancy Harvey Steorts, CPSC
The Honorable John R. Block, DOA
The Honorable Malcolm Baldrige, DOC
The Honorable Caspar W. Weinberger, DOD
The Honorable Terrel H. Bell, DED
The Honorable Donald Paul Hodel, DOE
The Honorable Margaret M. Heckler, HHS
The Honorable Samuel R. Pierce, Jr., HUD
The Honorable William French Smith, DOJ
The Honorable Elizabeth Hanford Dole, DOT
The Honorable William Ruckleshaus, EPA
The Honorable James M. Beggs, NASA
The Honorable Edward A. Knapp, NSF
The Honorable Harry N. Walters, VA

cc: Dr. James D. Shelton, AID

STAT

Dr. Peter W. Preuss, CPSC
Dr. Albert Esch, CPSC
Dr. Walter Mertz, DOA
Dr. John A. Simpson, DOC
Capt. James Vorosmarti, DOD
Dr. Edward B. Glassman, DED
Dr. J. W. Thiessen, DOE
Dr. Charles R. McCarthy, HHS
Dr. Stuart L. Nightingale, HHS
Mr. Arthur S. Newburg, HUD
Mr. Kevin R. Jones, DOJ
Mr. Bill L. Long, DOS (Ex Officio)
Dr. Ayub K. Ommaya, DOT
Dr. Hugh W. McKinnon, EPA
Dr. Arnauld E. Nicogossian, NASA
Dr. Richard T. Louttit, NSF
Mr. Richard Eisinger, OMB (Ex Officio)
Mr. Jerry Fill, OMB (Ex Officio)
Dr. Bernadine H. Bulkley, OSTP (Ex Officio)
Dr. Earl X. Freed, VA

 83-3724/2

Central Intelligence Agency

Washington, D.C. 20505

25 AUG 1983

The Honorable G. A. Keyworth
Science Advisor to the President
360 Old Executive Office Building
Washington, D.C. 20500

Dear Dr. Keyworth:

I received your memorandum of 18 July 1983 concerning the protection of human research subjects. The Ad Hoc Committee which you chartered and which has been chaired by Dr. Edward N. Brandt, Jr., Assistant Secretary for Health in the Department of Health and Human Services (HHS), has performed a noteworthy service in its clear response to the recommendations of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research in the First Biennial Report of the Commission, published in December 1981.

The Central Intelligence Agency approves the response of the Ad Hoc Committee to the recommendations made by the President's Commission. The Agency is in full accord with the model policy proposed by the Ad Hoc Committee.

Please note that Intelligence Community agencies are unable to adopt the model policy without HHS concurrence, since Executive Order 12333 (Part 2, paragraph 12) directs that human research conducted under Intelligence Community auspices conform to HHS guidelines.

STAT [redacted] will represent the Central Intelligence Agency on the Inter-Agency Human Subjects Coordinating Committee of the Federal Coordinating Council for Science, Engineering and Technology.

Sincerely,

/S/ John N. McMahon

John N. McMahon
Acting Director of Central Intelligence

Enclosure:
Agency Concurrence

L-299 YF

AGENCY CONCURRENCE WITH MODEL POLICY ON HUMAN RESEARCH SUBJECTS

DEPARTMENT/AGENCY: Central Intelligence Agency

_____ Initials

1. This department/agency concurs with the model policy on human research subjects and agrees to implement the policy expeditiously through issuance of regulation or other appropriate policy guidance.

X Initials

2. This department/agency concurs with the model policy except for the departures below and agrees to implement the policy expeditiously through issuance of regulation or other appropriate policy guidance.

• **Departures:**

The Central Intelligence Agency is required by Executive Order 12333 to conform to the guidelines issued by the Department of Health and Human Services (HHS). Until HHS incorporates the model policy with respect to the Intelligence Community, CIA will not be able to follow the model policy. However, we fully concur with the principles established therein and trust that the model policy will be incorporated soon by HHS.

• **Justification for Departures:**

Executive Order 12333 of 4 December 1981.

3. **Expected Date for Policy Implementation:** In effect now.

Signature: /S/ John N. McMahon

Name : John N. McMahon

Title : Acting Director of Central Intelligence

Date :

Letter to The Honorable G. A. Keyworth

STAT DMS/PD/BMM [redacted] (24 Aug 83)

Distribution:

Orig - Addressee
1 - DCI
1 - DDCI
1 - ExDir
✓1 - Ex Registry
1 - OGC
1 - DDA
1 - D/MS
1 - Chairman/HSRP

83-3729/1

24 August 1983

MEMORANDUM FOR: Acting Director of Central Intelligence

STAT FROM: [redacted]
Chairman, Human Subjects Research Panel

SUBJECT: Items for Your Signature and Initials

1. Attached are two items for your signature:

a. A response to Dr. Keyworth's letter of 18 July 1983.

b. Agency Concurrence with Model Policy on Human Research Subjects.

2. The Human Subjects Research Panel recommends that you respond by initialing item b. The model policy would be simpler for the Agency to follow than the Health and Human Services (HHS) regulations. Discussion will continue with HHS toward the goal of orderly development of HHS regulations which direct that the Agency follow the model policy proposed by the Ad Hoc Committee.

STAT [redacted]

Attachments.

EXECUTIVE SECRETARIAT

Routing Slip

TO:		ACTION	INFO	DATE	INITIAL
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15	D/OEA				
16	C/PAD/OEA				
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18	AO/DCI				
19	C/IPD/OIS				
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21					
22					
	SUSPENSE	28 July 83			
		Date			

Remarks:

Please prepare response for DCI's signature.

Executive Secretary
25 July 83
Date

3637 (10-81)

STAT

THE WHITE HOUSE

WASHINGTON

July 18, 1983

MEMORANDUM FOR DISTRIBUTION

FROM: G. A. KEYWORTH

SUBJECT: Protection of Human Research Subjects: Approval of Response to Recommendations of the President's Commission

We are ready to approve an interagency Federal response to the recommendations of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research.

In its First Biennial Report, published in December of 1981, the President's Commission made several recommendations intended to improve the uniformity of Federal rules and policies pertaining to protection of human research subjects. The law which established the Commission requires departments and agencies affected by the recommendations to implement the recommendations or publish in the Federal Register their reasons for not doing so. Because the recommendations published in the Commission's First Biennial Report affected such a large number of departments and agencies, it was deemed desirable to establish an interagency committee to develop a coordinated response representing a consensus of the agencies involved. Accordingly, in March of 1982, I chartered the Ad Hoc Committee for the Protection of Human Subjects, chaired by Dr. Edward N. Brandt, Jr., Assistant Secretary for Health, in the Department of Health and Human Services (HHS), and comprising representatives of 17 departments and agencies including yours and several Ex Officio members (see list of current contacts based on Ad Hoc Committee membership (Tab A). It is the report of this Ad Hoc Committee which we can now endorse and approve (Tab B).

Model Policy

The first and most important of the Commission's recommendations calls for the President to require, through appropriate action, "that all federal departments or agencies adopt as a common core the regulations governing research with human subjects issued by the Department of Health and Human Services (codified as 45 CFR, Part 46), as periodically amended or revised, while permitting additions needed by any department or agency that are not inconsistent with these core provisions." In response to this recommendation, the Ad Hoc Committee has drafted a policy intended to serve as a model for all Federal departments and agencies that conduct,

L-299

support, or regulate human subjects research (Tab C). To the degree possible, it reflects the different statutes, policies, and practices of the various agencies involved. I believe it represents an excellent model for use by each agency. I realize, however, that some agencies may need to differ slightly from the model policy and have therefore provided a form for your use in indicating such departures (Tab D). The model policy, along with your indication of approval and necessary departures, will be published in the Federal Register.

Continuing Coordination

Recommendation 2 of the Report of the President's Commission calls for the President to "authorize and direct the Secretary of Health and Human Services to designate an office with government-wide jurisdiction to coordinate, monitor, and evaluate the implementation of all regulations governing research with human subjects of Federal departments that conduct, support, or regulate such research." Central to the Ad Hoc Committee's response to recommendation 2 is the designation of the Office for Protection from Research Risks within HHS to serve in a coordinating capacity with the advice of a proposed Interagency Human Subjects Coordinating Committee composed of representatives of all involved Federal departments and agencies. I support this recommendation which provides coordination by an office whose full-time focus is on these issues, while leaving final decision-making to each department and agency. I have every confidence that Federal departments and agencies will continue the excellent cooperation and information exchange manifested in development of the model policy. A proposed charter for the Interagency Committee is attached (Tab E). I ask you to designate an individual to represent your department or agency to serve on the Interagency Committee. That individual should be well acquainted with the role of your department or agency in research involving human subjects and be able to speak with authority concerning policy development in this area.

Approval

I would appreciate your response to this memorandum by July 29.

Your response should include:

1. Approval of the response to the Commission's recommendations (Tab B)

2. Approval of the model policy (Tab C), using the form required (Tab D)

3. Name of an individual you are appointing to represent your department or agency on the Interagency Human Subjects Coordinating Committee

Your continued cooperation in this endeavor is very much appreciated. OSTP staff contact on this subject is Dr. Carl M. Leventhal (395-3125).

Enclosures: Tab A - List of Current Contacts Based on Ad Hoc Committee Membership

Tab B - Response to the Recommendations of the President's Commission

Tab C - Model Policy for Protection of Human Research Subjects

Tab D - Sample Format for Comments and Expected Departures

Tab E - Proposed Charter for Interagency Human Subjects Coordinating Committee

DISTRIBUTION

The Honorable M. Peter McPherson, AID
The Honorable William Casey, CIA
The Honorable Nancy Harvey Steorts, CPSC
The Honorable John R. Block, DOA
The Honorable Malcolm Baldrige, DOC
The Honorable Caspar Weinberger, DOD
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The Honorable Donald Paul Hodel, DOE
The Honorable Margaret M. Heckler, HHS
The Honorable Samuel R. Pierce, Jr., HUD
The Honorable William French Smith, DOJ
The Honorable Elizabeth Dole, DOT
The Honorable William Ruckleshaus, EPA
The Honorable James M. Beggs, NASA
The Honorable Edward Knapp, NSF
The Honorable Harry N. Walters, VA

cc: Dr. James D. Shelton, AID

STAT [redacted]

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Dr. Albert Esch, CPSC
Dr. Walter Mertz, DOA
Ms. Arva Jackson, DOC
Capt. James Vorosmarti, DOD
Capt. Peter Flynn, DOD
Dr. Edward Glassman, DED
Dr. J. W. Thiessen, DOE
Dr. Susan Rose, DOE
Dr. Charles R. McCarthy, HHS
Dr. Stuart Nightingale, HHS
Mr. Arthur S. Newburg, HUD
Mr. Kevin R. Jones, DOJ
Dr. Ayub K. Ommaya, DOT
Mr. Donald Levine, DOT
Dr. Richard Hill, EPA
Dr. Gerald A. Soffen, NASA
Dr. Arnauld E. Nicogossian, NASA
Dr. Eloise E. Clark, NSF
Dr. Richard Louttit, NSF
Dr. Dorothy Rasinski, VA
Mr. William Walsh III, DOS
Mr. James F. Kelly, OMB
Mr. Gerald Fill, OMB
Dr. Richard Eisinger, OMB

7/11/84

Model Federal Policy for

Protection of Human Research Subjects

Sec.101 To What Does This Policy Apply?

(a) Except as provided in paragraph (b) below, this policy applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable to such research. This includes research conducted by federal civilian employees or military personnel, except that each department or agency head may adopt such procedural modifications as may be

appropriate from an administrative standpoint. It also includes research conducted, supported, or otherwise subject to regulation by the federal government outside the United States.

(1) Research that is conducted or supported by a federal department or agency whether or not it is regulated as defined in Sec.102(e) must comply with all sections of this policy.

(2) Research that is neither conducted nor supported by a federal department or agency but is subject to regulation as defined in Sec.102(e) must be reviewed and approved, in compliance with Secs.101, 102, and 107 through 117 of this policy, by an institutional review board (IRB) that operates in accordance with the pertinent requirements of this policy.

(b) Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
(i) information obtained is recorded in such a manner that human

subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing or employability.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior that is not exempt under paragraph (2), if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation studies, if wholesome foods without chemical additives are consumed or if a limited amount of a food is consumed that contains a food additive or agricultural chemical at or below a level approved by the Food and Drug Administration, the Environmental Protection Agency, or the Animal Plant Health Inspection Service of the U.S. Department of Agriculture.

(c) Department or agency heads retain final judgment as to whether a particular activity is covered by this policy.

(d) Department or agency heads may require that specific research activities or classes of research activities conducted, supported, or otherwise subject to regulation by the department or agency but not otherwise covered by this policy, comply with some or all of the requirements of this policy.

(e) Compliance with this policy requires compliance with pertinent federal laws or regulations which provide additional protections for human subjects.

(f) This policy does not affect any state or local laws or regulations which may otherwise be applicable and which provide additional protections for human subjects.

(g) This policy does not affect any foreign laws or regulations which may otherwise be applicable and which provide additional protections to human subjects of research.

(h) When research covered by this policy takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in this policy. [An example is a foreign institution

which complies with guidelines consistent with the 1975 World Medical Assembly Declaration (Helsinki II) issued either by sovereign states or by an organization whose function for the protection of human research subjects is internationally recognized.] In these circumstances, if a department or agency head determines that the procedures prescribed by the institution afford protections that are at least equivalent to those provided in this policy, the department or agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in this policy. Except when otherwise required by statute, Executive Order, or the department or agency head, notices of these actions as they occur will be published in the FEDERAL REGISTER or will be otherwise published as provided in department or agency procedures.

(i) Unless otherwise required by law, department or agency heads may waive the applicability of some or all of the provisions of this policy to specific research activities or classes of research activities otherwise covered by this policy. Except when otherwise required by statute or Executive Order, the department or agency head shall forward advance notices of these actions to the Office for Protection from Research Risks, Department of Health and Human Services (HHS), and shall also publish them in the FEDERAL REGISTER or in such other manner as provided in department or agency procedures.

Sec.102 Definitions.

(a) "Department or agency head" means the head of any federal department or agency and any other officer or employee of any department or agency to whom authority has been delegated.

(b) "Institution" means any public or private entity or agency (including federal, state, and other agencies).

(c) "Legally authorized representative" means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

(d) "Research" means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute "research" for purposes of this policy, whether or not they are conducted under a program which is considered research for other purposes. For example, some "demonstration" and "service" programs may include research activities.

(e) "Research subject to regulation," and similar terms are intended to encompass those research activities for which a federal department or agency has specific responsibility for regulating as a research activity, (for example, Investigational New Drug requirements administered by the Food and Drug Administration). It does not include research activities which are incidentally regulated by a federal

department or agency solely as part of the department's or agency's broader responsibility to regulate certain types of activities whether research or non-research in nature (for example, Wage and Hour requirements administered by the Department of Labor).

(f) "Human subject" means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. "Intervention" includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. "Interaction" includes communication or interpersonal contact between investigator and subject. "Private information" includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

(g) "IRB approval" means the determination of the IRB that the research has been reviewed and may be conducted at

an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

(h) "Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

(i) "Certification" means the official notification by the institution to the supporting department or agency, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

Sec.103 Assuring Compliance with This Policy - Research Conducted or Supported by Any Federal Department or Agency.

(a) Each institution engaged in research which is covered by this policy and which is conducted or supported by a federal department or agency shall provide written assurance satisfactory to the department or agency head that it will comply with the requirements set forth in this policy.

(b) Departments and agencies will conduct or support research covered by this policy only if the institution has an assurance approved as provided in this section, and only if the institution has certified to the department or agency head that the research has been reviewed and approved by an

IRB provided for in the assurance, and will be subject to continuing review by the IRB. Assurances applicable to federally supported or conducted research shall at a minimum include:

(1) A statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution, regardless of whether the research is subject to federal regulation. This may include an appropriate existing code, declaration, or statement of etnical principles, or a statement formulated by the institution itself. This requirement does not preempt provisions of this policy applicable to department- or agency-supported or regulated research and need not be applicable to any research exempted or waived under Secs.101(b) or (i).

(2) Designation of one or more IRBs established in accordance with the requirements of this policy, and for which provisions are made for meeting space and sufficient staff to support the IRB's review and recordkeeping duties.

(3) A list of the IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution; for example: full-time employee, part-time employee, member of governing panel or board,

stockholder, paid or unpaid consultant. Changes in IRB membership shall be reported to the department or agency head.

(4) Written procedures which the IRB will follow (i) for conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution; (ii) for determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review; and (iii) for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject.

(5) Written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head (i) any unanticipated problems or scientific misconduct involving risks to human subjects or others; (ii) any allegation or finding of serious or continuing noncompliance with this policy or the requirements or determinations of the IRB; and (iii) any suspension or termination of IRB approval.

(c) The assurance shall be executed by an individual authorized to act for the institution and to assume on behalf of the institution the obligations imposed by this policy and shall be filed in such form and manner as the department or agency head prescribes.

(d) The department or agency head will evaluate all assurances submitted in accordance with this policy through such officers and employees of the department or agency and such experts or consultants engaged for this purpose as the department or agency head determines to be appropriate. The department or agency head's evaluation will take into consideration the adequacy of the proposed IRB in light of the anticipated scope of the institution's research activities and the types of subject populations likely to be involved, the appropriateness of the proposed initial and continuing review procedures in light of the probable risks, and the size and complexity of the institution.

(e) On the basis of this evaluation, the department or agency head may approve or disapprove the assurance, or enter into negotiations to develop an approvable one. The department or agency head may limit the period during which any particular approved assurance or class of approved assurances shall remain effective or otherwise condition or restrict approval.

(f) In lieu of negotiating a separate assurance, individual department or agency heads shall accept the existence of a current assurance, appropriate for the research in question, approved by and on file with the Office for Protection from Research Risks, HHS.

(g) Certification is required when the research is supported by a federal department or agency and not otherwise

exempted or waived under Secs.101(b) or (i). Along with the submission of an application or proposal for approval or support, an institution with an approved assurance covering the research shall certify that the application or proposal has been reviewed and approved by the IRB. Institutions without an approved assurance covering the research shall certify within 30 days after receipt of a request for such a certification from the department or agency, that the application or proposal has been approved by the IRB. If the certification is not submitted within these time limits, the application or proposal may be returned to the institution.

Sec.104 Section Reserved.

Sec.105 Section Reserved.

Sec.106 Section Reserved.

Sec.107 IRB Membership.

(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition

to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

(b) Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

(c) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

(d) No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

(e) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

Sec.108 IRB Functions and Operations.

In order to fulfill the requirements of this policy each IRB shall:

(a) Follow written procedures in the same detail as described in Sec.103(b)(4) and, if applicable, Sec.103(b)(5).

(b) Except when an expedited review procedure is used (see Sec.110), review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

Sec.109 IRB Review of Research.

(a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy.

(b) An IRB shall require that information given to subjects as part of informed consent is in accordance with Sec.116. The IRB may require that information, in addition to that specifically mentioned in Sec.116, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

(c) An IRB shall require documentation of informed consent or may waive documentation in accordance with Sec.117.

(d) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the

proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

(e) An IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

Sec.110 Expedited Review Procedures for Certain Kinds of Research Involving No More than Minimal Risk, and for Minor Changes in Approved Research.

(a) The Secretary, HHS, has established, and published in the FEDERAL REGISTER, a list of categories of research that may be reviewed by the IRB through an expedited review procedure. The list will be amended, as appropriate after consultation with other departments and agencies, through periodic republication by the Secretary, HHS, in the FEDERAL REGISTER.

(b) With the approval of department or agency heads, an IRB may use the expedited review procedure to review either or both of the following: (1) some or all of the research appearing on the list and found by the reviewers to involve no more than minimal risk, (2) minor changes in previously approved research during the period for which approval is authorized. Under an expedited review procedure, the review

may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in Sec.108(b).

(c) Each IRB which uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure.

(d) The department or agency head may restrict, suspend, terminate, or choose not to authorize an institution's or IRB's use of the expedited review procedure.

Sec.111 Criteria for IRB Approval of Research.

(a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

(1) Risks to subjects are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by Sec.116.

(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by Sec.117.

(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

Sec.112 Review by Institution.

Research covered by this policy that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.

Sec.113 Suspension or Termination of IRB Approval of Research.

An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head.

Sec.114 Cooperative Research.

Cooperative research projects are those projects covered by this policy which involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy. With the approval of the department or agency head, an institution participating in a cooperative project may enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort.

Sec.115 IRB Records.

(a) An institution, or when appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:

(1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

(2) Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

(3) Records of continuing review activities.

(4) Copies of all correspondence between the IRB and the investigators.

(5) A list of IRB members in the same detail as described in Sec.103(b)(3).

(6) Written procedures for the IRB in the same detail as described in Secs.103(b)(4) and 103(b)(5).

(7) Statements of significant new findings provided to subjects, as required by Sec.116(b)(5).

(b) The records required by this policy shall be retained for at least 3 years, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the department or agency at reasonable times and in a reasonable manner.

Sec.116 General Requirements for Informed Consent.

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language

understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) below, in seeking informed consent the following information shall be provided to each subject:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation

as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(6) The approximate number of subjects involved in the study.

(c) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

(1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

(2) The research could not practicably be carried out without the waiver or alteration.

(d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) The research involves no more than minimal risk to the subjects;

(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

(3) The research could not practicably be carried out without the waiver or alteration; and

(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

(e) The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

(f) Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.

Sec.117 Documentation of Informed Consent.

(a) Except as provided in paragraph (c) below, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

(b) Except as provided in paragraph (c) below, the consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by Sec.116. This form may be read to

the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

(2) A "short form" written consent document stating that the elements of informed consent required by Sec.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the "short form."

(c) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

Sec.118 Applications and Proposals Lacking Definite Plans for Involvement of Human Subjects.

Certain types of applications for grants, cooperative agreements, or contracts are submitted to departments or agencies with the knowledge that subjects may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal. These include activities such as institutional type grants when selection of specific projects is the institution's responsibility; research training grants in which the activities involving subjects remain to be selected; and projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. These applications need not be reviewed by an IRB before an award may be made. However, except for research exempted or waived under Sec.101(b) or (i), no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved

by the IRB, as provided in this policy, and certification submitted to the department or agency.

Sec.119 Research Undertaken Without the Intention of Involving Human Subjects.

In the event research is undertaken without the intention of involving human subjects, but it is later proposed to involve human subjects in the research, the research shall first be reviewed and approved by an IRB, as provided in this policy, a certification submitted to the department or agency, and final approval given to the proposed change by the department or agency.

Sec.120 Evaluation and Disposition of Applications and Proposals for Research to be Conducted or Supported by a Federal Department or Agency.

(a) The department or agency head will evaluate all applications and proposals involving human subjects submitted to the department or agency through such officers and employees of the department or agency and such experts and consultants as the department or agency head determines to be appropriate. This evaluation will take into consideration the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained.

(b) On the basis of this evaluation, the department or agency head may approve or disapprove the application or proposal, or enter into negotiations to develop an approvable one.

Sec.121 Reserved.

Sec.122 Use of Federal Funds.

Federal funds administered by a department or agency may not be expended for research involving human subjects unless the requirements of this policy have been satisfied.

Sec.123 Early Termination of Research Support; Evaluation of Applications and Proposals.

(a) The department or agency head may require that department or agency support for any project be terminated or suspended in the manner prescribed in applicable program requirements, when the department or agency head finds an institution has materially failed to comply with the terms of this policy.

(b) In making decisions about supporting or approving applications or proposals covered by this policy the department or agency head may take into account, in addition to all other eligibility requirements and program criteria, factors such as whether the applicant has been subject to a termination or suspension under paragraph (a) of this section and whether the applicant or the person who would direct or has directed the scientific and technical aspects of an

activity has in the judgment of the department or agency head materially failed to discharge responsibility for the protection of the rights and welfare of human subjects (whether or not the research was subject to federal regulation).

Sec.124 Conditions.

With respect to any research project or any class of research projects the department or agency head may impose additional conditions prior to or at the time of approval when in the judgment of the department or agency head additional conditions are necessary for the protection of human subjects.

TAB C

Revised 7/2/84

RESPONSE TO RECOMMENDATIONS OF THE
PRESIDENT'S COMMISSION

Response of the Office of Science and Technology Policy (OSTP) to the Recommendations of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research in Protecting Human Subjects; the First Biennial Report on the Adequacy and Uniformity of Federal Rules and Policies, and their Implementation for the Protection of Human Subjects in Biomedical and Behavioral Research (December 1981).

This response is based on the work of the Ad Hoc Committee for the Protection of Human Research Subjects of the Federal Coordinating Council for Science, Engineering, and Technology which was modified to incorporate OSTP policy considerations in and accepted by affected Federal department and agency heads in June 1984.

Recommendation 1

The President should, through appropriate action, require that all federal departments or agencies adopt as a common core the regulations governing research with human subjects issued by the Department of Health and Human Services (codified at 45 CFR Part 46), as periodically amended or revised, while permitting additions needed by any department or agency that are not inconsistent with these core provisions.

(A timetable of 180 days should be established by the President to provide an incentive for the interagency group to resolve any remaining questions about the HHS core regulations and identify an initial set of special rules beyond the core that are needed by various departments and agencies. If action is not prompt, the Commission suggests that Congress enact legislation directing the Executive branch to establish by a specified date a uniform set of regulations under a lead agency.)

The Ad Hoc Committee agreed in principle with this recommendation and developed a model policy statement based upon adaptations of HHS regulations for the protection of human subjects involved in research (45 CFR 46). The Office of Science and Technology Policy has made several modifications to increase uniformity of procedures among the federal departments and agencies and to increase compatibility with other current federal policies.

The model policy represented the Ad Hoc Committee's attempt to meet the concerns of the Commission that unnecessary and confusing regulations

impose burdens on institutions that conduct or support research involving human subjects. The Committee attempted to make the model policy consistent with the HHS regulations while allowing for flexibility and adaptability in its application to the programs of diverse federal departments and agencies.

The Ad Hoc Committee believed that, insofar as possible, federal departments and agencies should employ consistent policies and procedures in dealing with nonfederal research institutions. Accordingly, the model policy was drafted in a mode that strives for uniformity in assurance and certification procedures; in all matters pertaining to the establishment, membership, functions and responsibilities of Institutional Review Boards (IRBs); and in procedural requirements including informed consent. Nevertheless, the model policy will allow agencies to continue to utilize time-tested directives and procedures in the conduct of their intramural research so long as these procedures are consistent with the model policy and adequately protect the rights and welfare of human research subjects.

Similarly, the policy is designed to apply to research conducted, supported or regulated by United States departments or agencies in foreign situations. However, department or agency heads may accept other recognized standards in lieu of this policy so long as these standards offer at least equivalent protections for research subjects.

The Ad Hoc Committee concurred with the findings of the President's Commission that there is already close correlation between the major provisions of the HHS regulations and current policies and procedures of other federal departments and agencies for protecting human subjects. The model policy is intended to further reduce the diversity so that nonfederal research

institutions will not have to face inconsistent or contradictory requirements in their dealings with federal departments and agencies. The Ad Hoc Committee fully expected that adoption of the policy will reduce the administrative burdens on institutions that conduct research involving human subjects.

The model policy document has been drafted in the form of a policy statement rather than in the form of a regulation so that it may be referenced by departments and agencies that will implement the policy within a reasonable time and in a manner customary to each department or agency. In the future, department or agency heads may amend their policies so long as they note in advance in the Federal Register or other appropriate publications the way in which their amendments relate to provisions of the model policy.

Assuming a department or agency adopts the model policy it will retain the flexibility to waive individual requirements if waiver decisions are published in advance in the Federal Register or other appropriate publication. The Ad Hoc Committee believed that instances of waiver will be infrequent, and the requirement that each waiver be published will prevent inappropriate use of the waiver authority.

Highlights of key elements of the model policy for federalwide use are as follows:

Consistency with HHS Regulations

As noted previously, the Ad Hoc Committee model policy is patterned after HHS regulations. The word "Secretary" has been changed to "department or agency head" throughout the draft. Most of the provisions of the following subject areas are the same in the model policy and HHS regulations:

(1) the characteristics of IRBs; (2) the role of IRBs in providing prior review of research protocols, including their duties and authorities in relation to investigators, to their institutions, and to the sponsors of research; (3) the standards and procedures that should govern IRB decision-making and investigators' behavior; (4) the provisions of assuring compliance with the policy; (5) the procedures for expedited review; (6) the provisions for obtaining and documenting informed consent; and (7) the provisions for early termination of research support and evaluation of applications. The following highlights the major areas in which there is a difference in the model policy and current HHS regulations.

Applicability

Sec. 101(a) specifies that

> "....[The policy] includes research conducted, supported, or otherwise subject to regulation by the federal government outside the United States.
> (1) Research that is conducted or supported by a federal department or agency whether or not it is regulated as defined in Sec. 102(e) must comply with all sections of this policy.
> (2) Research that is neither conducted nor supported by a federal department or agency but is subject to regulation as defined in Sec. 102(e) must be reviewed and approved, in compliance witnh Secs. 101, 102, and 107 through 117 of this policy, by an institutional review board (IRB) that operates in accordance with the pertinent requirements of this policy."

It should be noted that federal support of an activity does not necessarily render the policy applicable to that activity. Federal "support" must be used in "research" involving "human subjects" as defined in the policy. For example, a private physician who conducts research unrelated to the Medicaid program would not come under this policy solely because the services he/she provides some of his/her patients are reimbursed by Medicaid. Nor would a research project sponsored by a State agency be covered solely because nonresearch services administered by the same agency are federally reimbursed. Alternatively, if a private physician or a State agency does employ federal support for research